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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402				
			EXAMINER KERR, KATHLEEN M	
			ART UNIT 1652	PAPER NUMBER

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/988,384

Applicant(s)

SHERMAN ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 29-55, 61 and 62 is/are pending in the application.
- 4a) Of the above claim(s) 29, 30 and 42-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-41, 61 and 62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

☐ Draftsperson's Patent Drawing Review (PTO-948)

☐ Written Disclosure Statement(s) (PTO-1449 or PTO/SB/08)

☐ (s)/Mail Date 9/24/04.

4) ☐ Interview Summary (PTO-413)

Paper No(s)/Mail Date. \_\_\_\_\_

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: \_\_\_\_\_

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1-04)

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Part of Paper No./Mail Date 12102004

## **DETAILED ACTION**

### ***Application Status***

1. In response to the previous Office action, a non-final rejection (mailed on January 30, 2004), Applicants filed a response and amendment received on May 6, 2004 and subsequently on September 24, 2004. Said amendment amended Claim 39 and 61 and added new Claim 62. Thus, Claims 29-55 and 61-62 are pending in the instant Office action.

### ***Election***

2. New Claim 62 falls within the elected Group. Claims 29-55 and 61-62 are pending in the instant application. Claims 29, 30, and 42-55 are withdrawn from consideration as non-elected inventions. Claims 31-41 and 61-62 will be examined herein.

### ***Priority***

3. As previously noted, the instant application requested the revival of PCT/US99/14398 filed June 25, 1999, which application was abandoned after 20 months of filing (no formal demand for examination was filed by Applicants). Said petition was granted in a paper mailed on April 19, 2004.

The instant application has additionally requested priority via the PCT/US99/14398 to U.S. application 09/105,537 filed on June 26, 1998 wherein the PCT is a continuation-in-part of 09/105,537; said priority is granted herein. However, Claims 31-41 and 61-62 lack support in 09/105,537. Thus, the filing date of the PCT is now considered the earliest effective filing date for the pending claims, that is June 25, 1999.

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***Information Disclosure Statement***

4. The information disclosure statement filed on September 24, 2004 has been reviewed, and its references have been considered as shown by the Examiner's initials next to each citation on the attached copy.

Additionally, Applicant is reminded that information disclosure is for the purpose of disclosing only that information which **bears on the patentability of the claims to be examined** (see 37 C.F.R. § 1.56 and M.P.E.P. § 2000). Background information is best cited in the specification but not expressly listed on the information disclosure so that particularly relevant articles are plain during examination and not lost in 8 pages of references.

***Compliance with the Sequence Rules***

5. By virtue of Applicant's amendment to the specification, the instant application now fully complies with the sequence rules. The new sequence listing, in computer readable form and paper copy, filed on May 6, 2004 containing 62 sequences has been entered.

***Withdrawn - Objections to the Specification***

6. Previous objection to the specification for having inconsistent references is withdrawn by virtue of Applicant's amendment.

***Maintained - Objections to the Specification***

7. Previous objection to the specification because the title is not descriptive is maintained. Applicant's new title "Promoter for Methymycin and Pikromycin" is not appropriately

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descriptive because the claims are drawn to a nucleic acid sequence that is a promoter of the methymycin/pikromycin PKS gene cluster. A new title is required.

8. Previous objection to the Abstract for not completely describing the disclosed subject matter (see M.P.E.P. § 608.01(b)) is maintained. Firstly, the amendment was not appropriate filed and could not be entered; amendments to the Abstract must be on a separate sheet of paper. Secondly, the source species, *Streptomyces venezuelae*, is still missing from the abstract and is crucial in describing the claimed subject matter. Correction is required.

9. Previous objection to the specification for the following inconsistencies with respect to the Drawings and their Brief Description in the text is maintained, in part:

- a) corrected
- b) corrected
- c) corrected
- d) corrected
- e) corrected
- f) On page 17, Figures 41A-41F must be described, not just Figure 41.

No correction to the description of Figure 41 has been made. Correction and/or clarification on are required.

***Withdrawn - Claim Rejections - 35 U.S.C. § 112***

10. Previous rejection of Claims 39-41 and 61 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "leader sequence of pikAI" is withdrawn by virtue of Applicant's removal of said term.

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11. Previous rejection of Claim 61 under 35 U.S.C. § 112, second paragraph, as being indefinite for terms like "a pikAI gene" and "a pikAII gene" is withdrawn by virtue of Applicant's amendment.

***Maintained - Claim Rejections - 35 U.S.C. § 112***

12. Previous rejection of Claims 31-41 and 61 under 35 U.S.C. § 112, first paragraph, written description (pikA promoter), is maintained; Claim 62 is added herein. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that the pikA promoter is described on page 75. The Examiner finds such a reference not on page 75, but on pages 72-73 (the reference on page 75 merely mentions the promoter). This reference notes that the pikA promoter (PpikA) of the gene cluster that is SEQ ID NO:5 can be found between pikR1 and pikA1. The instant claims are drawn not only to this species but also to *any* pikA promoter. Only one species has been described and this species is not representative of the entire genus because:

To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these. (see *Enzo Biochemical*, 62 USPQ2D 1289)

Claim 62 does little to ease this discrepancy by citing any EcoRV-EcoRI fragment of SEQ ID NO:5, which is 37,948 base pairs with likely numerous of such fragments. Without a structure/function relationship for a pikA promoter, this broad structural limitation does not

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sufficiently limit the claimed invention such that the specification adequately described the claimed scope.

13. Previous rejection of Claims 36, 39-41, and 61 under 35 U.S.C. § 112, first paragraph, written description (TEII domain) is maintained. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that the TEII domain is indeed described in Figures 29 and 31 and 46C-D; the Examiner does not disagree. The Examiner previously stated that specific TEII domains were described in the instant specification. The lack of written description is of the claimed genus of *any* TEII domain. As previously noted,

"In the instant specification, a gene encoding a TEII domain is described in Table 2, for example. The genus of all TEII domains is not described except for its use in the claims. The art does not describe such a genus either. Thus, one of skill in the art would be unable to predict the structure of other members of this genus by virtue of the instant disclosure."

***Withdrawn - Claim Rejections - 35 U.S.C. § 102***

14. Previous rejection of Claims 31-41 and 61 under 35 U.S.C. § 102(b) as being anticipated by WO 00/00620 (Sherman *et al.*) is withdrawn by virtue of the granting of priority to the PCT application by means of the petitioned revival.

15. Previous rejection of Claim 31 under 35 U.S.C. § 102(b) as being anticipated by Xue *et al.* is withdrawn. As noted above, the earliest effective date for the pending claims is June 25, 1999 rendering Xue *et al.* (October, 1998) less than one year prior to the effective date of the

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pending claims. Xue *et al.* is not "by others" as all the inventors are authors; thus, Xue *et al.* is not available as prior art under 35 U.S.C. § 102(a).

## NEW ISSUES

### *Claim Rejections - 35 U.S.C. § 112*

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claim 61 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 40 is wholly unclear. What gene is to be disrupted or replaced? Claim 61 depends from Claim 40, which depends from any of Claims 32-39 - none of these claims require genes in the DNA molecule claimed. Only as the claim depends from Claim 38 is a gene even indicated since Claim 38 requires KS-AT-ACP-TE domains. Moreover, the KS, AT, KR, ACP limitation is wholly unclear since this is not what is required in the previous claims.

Clarification on all these points is required.

### *Summary of Pending Issues*

17. The following is a summary of the issues pending in the instant application:

- a) The specification stands objected to because the title is not descriptive.
- b) The Abstract stands objected to for not completely describing the disclosed subject matter.
- c) The specification stands objected to for the following inconsistencies with respect to the Drawings and their Brief Description in the text.
- d) Claims 31-41 and 61 stand rejected under 35 U.S.C. § 112, first paragraph, written description (pikA promoter).
- e) Claims 36, 39-41, and 61 stand rejected under 35 U.S.C. § 112, first paragraph, written description (TEII domain).
- f) Claim 61 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.



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***Conclusion***

18. Claims 31-41 and 61-62 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr  
Primary Examiner  
Art Unit 1652

December 10, 2004